SUMMARY OF THE
NELAC BOARD OF DIRECTORS AND CHAIRS MEETING
NOVEMBER 18, 2002

The Board of Directors of the National Environmental Laboratory Accreditation Conference (NELAC) met in Santa Fe, NM on November 18, 2002, at 9:30 a.m. Mountain Standard Time (MST), immediately prior to the Opening Plenary session of NELAC 8i. Chairperson Dr. Paul Kimsey of the California Department of Health Services led the meeting. The agenda for this meeting is shown in Attachment A, new action items are shown in Attachment B, incomplete action items from past meetings are shown in Attachment C, and a list of participants is shown in Attachment D.

APPROVAL OF MINUTES

Dr. Kimsey opened the meeting by asking each person to introduce themselves. It was agreed that review of the minutes and action items from the November 14, 2002, meeting should be deferred to the next regularly scheduled meeting of the Board.

AARB REPORT

Dr. Kimsey introduced Ms. Judy Duncan, chair of the Accrediting Authority Review Board, noting that the AARB report and summary, and the review checklist, had been distributed with the agenda. Ms. Duncan briefly reviewed noteworthy issues of the report (Attachment E). She noted that there is progress evident in this program that is still in development.

COMMITTEE UPDATES

Each committee chair reviewed final preparations and issues for their NELAC 8i committee session (details had been discussed earlier - see minutes of October 10, 2002).

CONFERENCE UPDATE

Ms. Barbara Giesler, representing the NELAC 8i co-host, the New Mexico Environment Department, gave an update on meeting details. She noted that a total of 199 had registered

SESSION LOGISTICS

Dr. Gene Tatsch, representing EPA's support contractor, RTI International, reviewed preparations that have been made in support of the committee sessions, the location of the RTI workroom, and the roles of committee chairs in the processes for completing meeting-specific deliverables in a timely and accurate manner.

LABORATORY ACCREDITATION MODEL STUDY

Dr. Kimsey briefly reviewed the "Laboratory Accreditation Model Study"prepared by EPA (Attachment F), noting that the full report was included with the meeting agenda. He also noted that detailed discussion would be delayed until the next Board meeting.

OTHER BUSINESS

No additional business was discussed.

NEXT MEETING

The next meeting of the Board of Directors is scheduled as a teleconference on Thursday, December 12, 2002, at 1:30 p.m.., Eastern Standard Time (EST).

Attachment A

NELAC BOARD OF DIRECTORS
AGENDA
November 18, 2002
Santa Fe, NM

1. Approval of Minutes of November 14, 2002, Meeting * - *Paul Kimsey*
2. AARB Report * - *Judy Duncan*
3. Committee Updates - *Chairs*
4. Conference Update - *Barbara Giesler*
5. Session Logistics - *Gene Tatsch*
6. Laboratory Accreditation Model Study *- *Paul*
7. Old Business
8. New Business

* Attachment

Attachment B

NEW ACTION ITEMS
NELAC BOARD OF DIRECTORS/CHAIRS
NOVEMBER 18, 2002

Item No.	Action	Status
1	Review Minutes of November 14, 2002	Due 12/18/02
2	Review EPA's "Laboratory Accreditation Model Study"	Due 12/18/02

Attachment C

ACTION ITEMS FROM PREVIOUS MEETINGS
NELAC BOARD OF DIRECTORS
NOVEMBER 18, 2002

NO.	MEETING DATE	ACTION	STATUS
4	8/8/02	Dr. Kimsey to contact NELAC Chairs regarding which standards development organization their committee will join.	In process
8	9/12/02	Ms. Hankins will recommend to the Regional Lead Evaluators that the observer use a cross-walk along with the state's checklist.	In process
11	10/10/02	Ms. Labie will check with Sherry Clay on use the OGWDW and ECOS endorsements.	ASAP
13	10/10/02	Mr. Kantor will check on the status of a list of interested SDOs for discussion at the next meeting.	Due Nov 14
14	11/14/02	Dr. Kimsey will review and clarify the essential role of EPA in his remarks during the Opening Plenary session of NELAC 8i.	11/18/02
15	11/14/02	The Board will draft a letter to EPA reiterating their consensus of the role of EPA in NELAC, based on discussions during NELAC 8i.	following NELAC 8i
16	11/14/02	Ms. Aurora Shields will have her good copy of the ECOS letter (see last month's minutes) scanned for this use.	ASAP

Note: items that were noted as "Complete" in previous minutes have been deleted from this list.

Attachment D

LIST OF PARTICIPANTS
BOARD OF DIRECTORS AND CHAIRS MEETING
NOVEMBER 18, 2002

Name	Affiliation	Address
Dr. Paul Kimsey Chair	CA Department of Health Services	T: (510)307-8419 F: (510)412-5848 E: pkimsey@dhs.ca.gov
Mr. R. Wayne Davis Chair-Elect	SC/DHEC Office of Environmental Lab Certification Transition Committee, Chair	T: (803)896-0972 F: (803)896-0850 E: davisrw@dhec.state.sc.us
Ms. Silky Labie Past-Chair	FL Dept. of Environmental Protection Small Organizations Committee, Chair Nominating Committee, Chair	T: (850)488-2796 F: (850)922-4614 E: silky.labie@dep.state.fl.us
Ms. Jeanne Hankins Director	USEPA/ORD	T: (919)541-1120 F: (919)541-4261 E: hankins.jeanne@epa.gov
Mr. Edward Kantor Executive Secretary	USEPA/ORD	T: (702)798-2690 F: (702)798-2261 E: kantor.edward@epa.gov
Ms. Ann Marie Allen (absent)	MA Dept. of Environmental Protection	T: (978)682-5237 F: (978)688-0352 E: ann.marie.allen@state.ma.us
Mr. Thomas Maloney	USGS National Water Quality Laboratory	T: (303)236-3460 F: (303)236-3499 E: tmaloney@usgs.gov
Mr. Richard Sheibley	PA Department of Enviromental Protection	T: (717)705-2425 F: (717)783-1502 E: rsheibley@state.pa.us
Mr. Joe Slayton	USEPA/Region 3	T: (410)305-2653 F: (410)305-3095 E: slayton.joe@epa.gov
Mr. Gleason Wheatley	KY/Dept. of Environmental Services	T: (502)564-6120 F: (502)564-8930 E: gleason.wheatley@mail.state.ky.us
Ms. Aurora Shields	KS Dept. of Health and Environment	T: (785)296-6198 F: (785)296-8068 E: ashields@kdhe.state.ks.us
Dr. Ken Jackson (Invited Guest)	NY Environmental Laboratory Approval Program Program Policy & Structure Committee, Chair	T: (518) 485-5570 F: (518) 485-5568 E: jackson@wadsworth.org
Ms. Susan Wyatt (absent)	Accreditation Process Committee, Chair	T: (612) 676-5674 F: (612) 676-5514 E: susan.wyatt@health.state.mn.us
Mr. Louis Johnson	Accrediting Authority Committee, Chair	T: (225) 765-2405 F: (225) 765-2408 E: louis_j@deq.state.la.us
Dr. Bart Simmons	Field Activities Committee, Chair	T: (510) 540-3112 F: (510) 540-2305 E: dtscr2.bsimmons@dtsc.ca.gov
Ms. Sherry Clay	Membership and Outreach Committee, Chair	T: (512) 458-7318 F: (512) 458-7294 E: sherry.clay@tdh.state.tx.us
Mr. Matt Caruso	National Database Committee, Chair	T: (518) 485-5570 F: (518) 485-5568 E: caruso@wadsworth.org

Name	Affiliation	Address
Mr. Alfredo Sotomayor	On-Site Assessment Committee, Chair	T: (608) 266-9257 F: (608) 266-5226 E: sotoma@dnr.state.wi.us
Ms. RaeAnn Haynes	Proficiency Testing Committee, Chair	T: (503) 229-5983 F: (503) 229-6924 E: haynes.raeann@deq.state.or.us
Mr. David Mendenhall	Quality Systems Committee, Chair	T: (801) 584-8469 F: (801) 584-8501 E: davidmendenhall@utah.gov
Mr. Kevin Coats	Regulatory Coordination Committee, Chair	T: (402) 697-2563 F: (402) 697-2595 E: kevin.h.coats@usace.army.mil
Dr. Gene Tatsch (Contractor Support)	RTI International	T: 919-541-6930 F: 828-628-0659 E: cet@rti.org

October 4, 2002

Jeanne Hankins
NELAP Director
US EPA (E234-05)
4930 Old Page Road
Research Triangle Park, NC 27709

Dear Jeanne:

Subject: AARB Annual Review of NELAP

On September 4-6, 2002 Dan Hickman, Carl Kircher and Judy Duncan of the Accrediting Authority Review Board (AARB) performed a review of the EPA/National Environmental Laboratory Accreditation Program's (NELAP) Accrediting Authority (AA) recognition process for consistent and appropriate application of the National Environmental Laboratory Accreditation Conference (NELAC) standards. The review took place in the offices of Edward Kantor, NELAP Executive Secretary in Las Vegas. This is the designated repository for NELAP's central file for program records. In addition to Ms. Hankins and Mr. Kantor, other EPA staff present for portions of the review included Jan Contreras and Brian Schumacher.

Ms. Duncan's letter of July 26, 2002 informed you of the AARB members appointed to conduct the annual review and questioned if any other assessment team member presented a potential conflict-of-interest. None were identified.

The annual review was conducted using the quality system and assessment checklist that AARB had previously compiled to assist with this task. The checklist items were based on Chapter 6 – Accrediting Authority in the NELAC Standards.

The following items are included as attachments to this letter:

- A copy of the checklist completed at the time of the review.
- A table completed at the time of the assessment that notes significant milestones of the accreditation process and the date of the record that documents each milestone. The table is completed for each of the state organizations that currently are approved AAs.
- Attachment B of the AARB July 2002 Annual Report (pages 10 and 11). This attachment summarizes recommendations from past AARB reviews of NELAP.

The AARB found that a number of recommendations made in previous years had been implemented by NELAP. In particular, we were pleased to note the creation of a central file for AA reviews. Findings and recommendations of the 2002 AARB review include the following:

1. The most significant finding and recommendation of the AARB review concerns Standard Operating Procedures and a Quality System (QS) for NELAP. The AARB knows of the following documents but they were not a part of the central file for NELAP.
   - Checklist to Determine AA Compliance with Renewal Requirements
   - NELAP Evaluation Team Selection Process
   - NELAP Evaluation Team SOP for On-Site Assessment of AAs
   - Questions to Assist the On-Site Evaluation Team in Conducting an Assessment of an AA
   - Manual for NELAP Evaluator Training for AA Recognition
   - NELAP AA Application File Folder Checklist
   - NELAC Operating Policies regarding NELAP
   - Recommended Format for Assessment Report

   NELAP should have a Quality System and these documents could be drawn from to develop one. At the present time, it is difficult to determine if the existing QS documentation is being followed or will be followed in the future. We can infer that these SOPs were used in that similar documentation exists from one EPA Region to another. However, the level of detail of the documentation varies widely so it is difficult to determine that the SOPs were followed uniformly.

2. The Completeness Review required in NELAC Standard 6.3.2(c) and Technical Review required in 6.3.3(a) were combined.
   - NELAC Standard 6.3.2(c)(4) requires NELAP to notify the AA in writing when the application is complete within seven calendar days of the date of such a determination. Other timelines for the review process begin at this point. There were no files to indicate that this notification was sent although there were files that indicated that communication took place to request additional information for some renewals.
   - NELAC Standard 6.3.2(c)(1) requires the use of a standardized checklist for Completeness Reviews. This was combined with the checklist for Technical Review.
   - Since the timelines for NELAP completion of the steps of the renewal process begin with notification to the AA of the Completeness Review, the AARB was unable to accurately determine whether timelines for review were met.

3. Documentation that the Evaluation Team independently reviewed the Application Technical Review Checklist prepared by the AA was inconsistent.
   - Three of ten renewal files had a separate Checklist completed by the Evaluation Team at the end of the review.
   - One can infer that the Evaluation Team actually reviewed each of the documents referenced in the Checklist submitted by the AA from the Deficiency Reports in most of the other seven cases but there is no specific documentation.
   - A suggestion would be to add a column to the Checklist for use by the Evaluation Team to document review of information provided by the AA.4.

4. NELAP needs a Document Control SOP to assure that all Regions have the same set of information to work from. The SOP should specify detailed document format (i.e. letter

or memo, specific details that must be included, etc.). For example the Application Technical Report should include:

- Letter or memo with a subject line.
- Significant steps of the review and date completed.
- Assessment Team members
- Assessment Checklist completed by the Assessment Team as well as the AA
- Itemized deficiencies with references to specific standards and suggested corrective actions.

Please note that similar recommendations were made by the AARB in reviews conducted in 2000 and 2001. Since NELAP relies upon staff located in the Regions to perform evaluations, if there is not a detailed SOP for document preparation and control, it is virtually impossible for staff responsible for file maintenance to identify and properly file documents. The same document never looks like another prepared by a different Evaluation Team.

The NELAP central files should contain copies of all NELAP SOPs and Checklists in addition to the files of AA reviews.

5. AARB recommends that NELAP prepare a roster of Qualified Evaluation Team members showing items included in 6.9.1(c)-(e). This will allow verification by the AARB review team that these requirements were met.

6. There were good examples of documentation from Evaluation Teams in Regions 2 and 3. The poorest documentation was from the Evaluation Team in Region 8.

7. The AARB noted that there were no files for Oregon's renewal because that evaluation is still not complete even though the application for renewal was submitted in September 2001. When Evaluation Teams are significantly behind in completion of reviews, as in this case that appears to be well outside of recommendations contained in the NELAC Standards, the AARB recommends that periodic status reports be provided to the AA.

8. The AARB noted the following inconsistencies in documentation of renewal reviews.
   - There was no specific recommendation from the Region to the Director to approve or deny renewal for New York. There is a letter that refers the matter the NELAP Director for resolution of issues.
   - The only documentation of a corrective action plan for California is in the form of a note in the recommendation letter from the Region that says that the AA provided a plan by telephone.
   - There was no record of NELAP Director notification to New Jersey that the renewal was approved. The Certificate of renewal was also missing from the file.
   - The file for the Utah renewal did not include an Application Technical Review Report or Corrective Action response from the AA.
   - None of the files contained copies of the NELAP invitation to renew AA approval. The AARB 2001 Annual Report indicates that this document was reviewed by the AARB. We recommend that copies be included in each of the renewal files to document that NELAC Standard 6.3.1(d)(1) was met.

- As noted in Item 2 above, none of the files contained an Application Completeness Checklist or a Completeness Letter.
- The files for New Jersey, New York and Pennsylvania were the only ones that contained a Quality Systems Checklist completed by the Evaluation Team. In all other cases the QS Checklists were those completed by the AA and submitted with the application for renewal.

9. The files for the renewals were inconsistent and some items were misfiled. This may be in most part because the files are newly consolidated and some e-mail items may not have been included. A NELAP AA Application File Folder Checklist has been prepared but lack of uniformity in the form of documents makes it difficult to determine which document is which.

10. Missing National Databases created problems with consistency among AAs. There are communication difficulties and states are currently helping by maintaining lists of labs and lists of fields of testing.

11. The AARB noted that the AA states are doing the job of NELAP with regard to databases for certified laboratories and fields of testing. Missing national databases have created problems with consistency among AAs. There are communication difficulties and states are currently maintaining lists of labs and lists of fields of testing.

12. The Certificates for renewals do not contain the following required elements required in NELAC Standard 6.7(b):
    - The date of the AA's most recent on-site assessment.
    - A statement that continued NELAP recognition depends on compliance with NELAC standards.

One final recommendation is that NELAP prepare a response to the recommendations contained in this and prior annual reviews performed by the AARB. A summary of those recommendations is attached.

Should you have any questions regarding the findings of the AARB Annual Review of NELAP, please contact me.

Sincerely,

Judith A. Duncan
Accrediting Authority Review Board Chair

c. AARB Members
Edward Kantor, NELAP Executive Secretary

Attachment F

Laboratory Accreditation Model Study

Prepared for David Friedman
November 12, 2002

Contract No. 68-W-99-041
Work Assignment No. 4-15

By
Versar, Inc.

Attachment F

Table of Contents

Introduction

The environmental monitoring community in the United States is in the process of establishing a national environmental laboratory accreditation program. The National Environmental Laboratory Accreditation Conference (NELAC), has been established for this purpose. Further, a set of accreditation and program operation standards have been adopted and the program has become operational. However, the question of how can such a program be best organized and funded is still being evaluated by the NELAC community. As part of EPA's efforts to assist in this endeavor, a study has been conducted to gather information on how other laboratory accreditation programs are organized, funded, and operated so that the NELAC community can evaluate alternative models and funding mechanisms.

This report provides the results of a survey of a variety of national laboratory accreditation programs (looking at programs both in the United States and in other countries) with an attempt to cover as many different approaches to such programs as possible. This report does not provide any recommendations, but simply provides the information in an objective, neutral manner.

The report contains information on each program in five areas, including: (1) initiation of the program, (2) characteristics of the program, (3) program operations, (4) funding, and (5) assessment and accreditation.

Laboratory Accreditation Bureau
3000 Dundee Road, Suite 302Northbrook, Illinois 60062
Phone: (847) 564 9660 or 1-877-676-2552
Fax: (847) 564 8120
E-mail: mail@l-a-b.com
http://www.l-a-b.com

A. Initiation of the Program

The L-A-B program was started in October 1999 by a group of investors who saw a need for additional accreditation bodies after the automotive industry initiated its requirements within the QS 9000 and TS 16949 standards. The QS 9000 standards are based on the requirements of three major American car manufacturers while the TS 16949 standards are inclusive of more global requirements. L-A-B was established to provide laboratory accreditation services to independent and captive testing and calibration laboratories across North America.

The program has consistently progressed and as of this date, nearly two hundred accreditations have been granted. The automotive industry continues to recognize the work of L-A-B, and other industries are beginning to do so as well. The number of laboratories interested in accreditation continues to grow as more laboratories become accredited.

The drivers for the continuance of the program include: (1) the automotive industry requirements that all testing and calibration laboratories be accredited if they are to be in the supply chain for their industry, (2) laboratories recognize that market demands are requiring them to become accredited, (3) since QS 9000 and TS 16949 are international standards and no longer simply a guide, there is now a common set of requirements available for application of a laboratory accreditation, and (4) there appears to be an economic advantage to a laboratory in being accredited.

Since the inception of L-A-B, the main thing that has changed is the growing market demand for the use of accredited laboratories.

B. Characteristics of the program

The primary fields of accreditation included in this program are calibration and testing in the following three areas: electrical, environmental, and mechanical. Various numbers are available on the overall size of the industry, but a guess, provided by Robert Levine, Managing Director of L-A-B, is that there are at least 14,000 laboratories in the USA alone (this number is not exclusive to automotive laboratories only). As of July 1, 2001, over a hundred laboratories have been accredited by L-A-B and many more are currently in the process. The L-A-B web site provides a comprehensive listing of those labs already accredited and those in the process.

The USA automotive industry has accepted L-A-B as an accreditation body

suitable for the purpose of demonstrating conformance of laboratories to the QS 9000 standard. For example, North American automakers require their QS 9000 registered suppliers to utilize accredited independent testing or calibration laboratories to audit compliance to ISO (International Organization for Standardization)/IEC (International Electrotechnical Commission) Guide 25 or ISO/IEC 17025. The requirements are applicable not only to direct suppliers to the automobile manufacturers, but extend to the subcontracted testing and calibration laboratories used by their suppliers.

ISO/TS 16949 requires that all suppliers comply with ISO 17025 and that all independent test and calibration lab sub-contractors be accredited to the standard.

L-A-B is in the process of achieving recognition through the National Cooperation for Laboratory Accreditation (NACLA).

C. Program operations

The main structure of L-A-B includes a Managing Director, a Technical Manager, an Office Manager, a Calibration Program Manager and an Accounting Manager. L-A-B assessors are all sub-contractors and there are 90 assessors qualified by L-A-B for their respective fields of expertise. Additionally, there is a Technical Advisory Committee made up of volunteers who provide advice on the operation of the program and approval of operating policies and programs. The volunteers are usually either members of L-A-B's assessor team or are experts in the field of reference for the particular technical committee. The volunteers are selected based on their knowledge and their willingness to offer their time at no expense to L-A-B.

Day to day operations of the program are shared by the Managing Director (administrative responsibilities) and the two technical staff: the Technical Manager and the Calibration Program Manager. Oversight is provided through: (1) acceptance from the user groups (e.g. automotive industry), (2) other accreditation bodies (corrective action complaints–usually result from a complaint from a third party), (3) other laboratories (corrective action complaints), and (4) an evolving process put forward by NACLA for the recognition of accreditation bodies for the USA. All accreditation bodies must operate in conformance with ISO Guide 58 and L-A-B states that its program conforms. An analysis comparing L-A-B's operations against Guide 58 requirements is available from L-A-B.

The standard used by L-A-B is ISO/IEC 17025. It has been developed using the international standards writing bodies ISO and IEC procedures and processes. In the case of primary and secondary suppliers to the automotive industry, accreditation to ISO/IEC 17025 is mandatory. The remainder of compliance incentives are strictly voluntary.

D. Funding

The source of income is from the laboratories becoming accredited. The initial application fee is $850 which covers the cost of reviewing the documents submitted by the client and

assigning/coordinating the assessor assigned to the client. The annual fee for the first field of testing/laboratory site is $1,200 and includes the cost of maintaining the credentials, L-A-B staff, Technical Advisory Committee participation and maintenance of the L-A-B web site. An accreditation is valid for three years. There is an additional charge of $820 for each field or site beyond the first one. There is an additional charge of $1,350 for the preparation/report of the assessor's review of the laboratory's quality manual and all of its supporting documentation. The laboratory is also charged $820 per day for the assessor's time when on a site visit.

E. Assessment and Accreditation

Assessors are chosen based on an application process which looks at the potential assessor's experience actually conducting the test, inspections, and calibrations. Once the assessor is accepted based on the application process, they complete a four-day course covering measurements uncertainty, ISO/IEC 17025, and the program requirements of L-A-B. There is an examination given at the end of the course which must be passed. The assessor is also periodically observed during an assessment by L-A-B's Technical Manager.

Accreditation through the L-A-B program involves a visit every 12 months in order to maintain the accreditation. After initial accreditation, an assessor conducts a surveillance visit in each of the following 2 years. In the 3rd year, a complete reassessment is performed after which the accreditation is renewed for another 3 years.

A laboratory may appeal a L-A-B decision not to grant, suspend, or withdraw accreditation. This appeal has to be sent to L-A-B, in writing, within 30 days of notification of the decision. The appeal has to state the reasons why the laboratory believes it should receive or retain its accreditation. The Managing Director then appoints a panel of three persons from the Technical Advisory Committee to investigate the appeal. The selection process is designed to assure that the Appeals Panel members have the proper qualifications, and do not have a conflict of interest. All efforts are made to assure that the panel members are acceptable to all parties concerned. The panel investigates the appeal and determines whether the appeal is justified or not. Based on the recommendation of the panel, L-A-B may decide to overturn the recommendation of the Accreditation Committee, and grant recognition to the laboratory. In the case of an appeal to a decision to suspend or withdraw accreditation, the accreditation remains in effect during the appeal process.

Many laboratories have had their accreditation either suspended or terminated for a number of reasons, including (1) non-payment, (2) non-compliance with QS 9000/TS 16949 standards, (3)non-compliance with L-A-B's requirements, (4) moved to another accreditation body, and (5) no longer desires accreditation. An estimated 2% of accredited laboratories lose their accreditation for reasons other than non-payment of fees. Some have had their accreditation put back on active status after meeting the requirements (payment of outstanding invoice, meets requirements, etc.).

National Voluntary Laboratory Accreditation Program
(NVLAP)

National Institute of Standards and Technology
100 Bureau Drive, MS 2140
Gaithersburg, Maryland 20899-2140
Telephone: 301-975-4016
Fax: 301-926-2884
E-Mail: NVLAP@nist.gov
http://www.nist.gov/nvlap

A. Initiation of the Program

For many years the Department of Commerce, through the National Bureau of Standards (NBS), assisted in resolving the need for testing laboratory evaluation. Since 1929, NBS has participated with Federal and State agencies and private interests in developing evaluation criteria for testing laboratories and in providing on-site examinations, proficiency test samples, calibrated standards, and reference materials. More than one thousand laboratories working in areas such as concrete, cement, asphalt, paper, fiberboard, color and appearance, rubber, and forensic testing of fabric flammability make use of these NBS services.

In 1969, the American Society for Testing and Materials (ASTM) requested that NBS participate with ASTM and other interests in establishing a testing laboratory examination service over a broad range of product areas wherever needs developed. The ASTM proposal for a Technical Inspection Service led to an NBS study. This study supported the ASTM proposal but suggested that the developing needs of domestic and international commerce and the public health and safety would be benefitted by a means that also would provide a public recognition of testing laboratories found qualified on the basis of such inspections.

In September 1970, the National Bureau of Standards convened a conference to consider a proposal for a voluntary national testing laboratory accreditation program that, in addition to providing laboratory examination services, would issue accreditations to provide national recognition to those laboratories found to be competent in conducting certain tests. An ad hoc committee appointed by the conference developed the concept of a national voluntary laboratory accreditation program, and from 1972-1974, this concept received a broad informal review. Because of evident interest in a national program for testing laboratory accreditation, such as that indicated by members of the U.S. Congress and the National Business Council for Consumer Affairs, the Department of Commerce decided to initiate such a voluntary program in cooperation with other government agencies and with the private sector.

In May 1975, the Department publicly announced proposed procedures for a national voluntary laboratory accreditation program and invited written comments and participation in public hearings by all interested parties. More than 150 respondents, including Federal and State agencies, technical societies and trade associations, industries, testing laboratories, and individuals provided oral testimony or written comments on the proposal during the public review period that followed.

On the basis of this public review, the proposed procedures were revised and the National Voluntary Laboratory Accreditation Program (NVLAP) was established by notice in the FEDERAL REGISTER, February 25, 1976. These procedures are set out in Title 15, Part 7 of the Code of Federal Regulations (15 CFR 7).

NVLAP continues to be an accreditation organization for many reasons including the fact that it is a governmentally endorsed program and market driven. NVLAP responds to requests from government and industry to develop programs that are deemed necessary to fulfill government needs (e.g., The Asbestos Hazardous Emergency Response Act) or industry needs.

B. Characteristics of the program

NVLAP accredits laboratories in a variety of fields including: (1) Calibration Laboratories (Dimensional, Electromagnetics - DC/Low Frequency, Electromagnetics - RF/Microwave, Ionizing Radiation, Mechanical, Optical Radiation, Thermodynamics, Time and Frequency), (2) Chemical Calibration (Certifiers of Spectrophotometric NTRMs and Providers of Proficiency Testing), (3) Dosimetry (Ionizing Radiation Dosimetry Electromagnetic Compatibility and Telecommunications and Emissions, Immunity, MIL-STD-462,Safety, and Telecommunications, (4) Environmental (Asbestos Fiber Analysis including the PLM Test Method and the TEM Test Method), (5) Fasteners and Metals, (6) Information Technology Security Testing (Common Criteria Testing and Cryptographic Module Testing), (7) Product Testing (Acoustical Testing Services, Carpet and Carpet Cushion, Commercial Products Testing, Construction Materials Testing, Efficiency of Electric Motors, Energy Efficient Lighting Products, Thermal Insulation, and Wood Based Products)

NVLAP identifies its accredited laboratories in a published directory, NIST Special Publication 810, and on their web site. Labs are listed according to field of accreditation and many can be found in more than one category.

NVLAP is stated to be in full conformance with the standards of ISO and IEC, including ISO/IEC 17025 and Guide 58.

C. Program operations

The National Institute of Standards and Technology (NIST) administers NVLAP. NVLAP is comprised of a series of laboratory accreditation programs (LAPs) which are established on the basis of requests and demonstrated need. Each LAP includes specific calibration and/or test standards and related methods and protocols assembled to satisfy the unique needs for accreditation in a field of testing or calibration. NVLAP accredits public and private laboratories based on evaluation of their technical qualifications and competence to carry out specific calibrations or tests.

Accreditation criteria are established in accordance with the U.S. Code of Federal Regulations (15 CFR 285), NVLAP Procedures and General Requirements, and encompass the requirements of ISO/IEC 17025 and the relevant requirements of ISO 9002. Accreditation is granted following successful completion of a process which includes submission of an application and

payment of fees by the laboratory, an on-site assessment, resolution of any deficiencies identified during the on-site assessment, participation in proficiency testing, and technical evaluation. The accreditation is formalized through issuance of a Certificate of Accreditation and Scope of Accreditation and publicized by announcement in various government and private media.

Day to day operations are undertaken by a staff of 17 people and oversight is provided by the National Institute of Standards and Technology of the Department of Commerce, but NVLAP does have independence for accreditation decisions.

NVLAP procedures have been developed to ensure consistency with international standards and guidelines, specifically those found in ISO/IEC 17025: 1999 and ISO/IEC 58: 1993. NVLAP evaluates labs according to ISO/IEC 17025 to perform specific test methods. The specific tests and calibrations or standards to be included in a LAP are determined by an open process during the establishment of the LAP. Technical requirements are based on relevant and impartial expert advice which is obtained through one or more public workshops or through some other suitable means.

NVLAP does not require participation in its program, but NVLAP accreditation is required by several regulations (i.e. asbestos testing, dosimetry testing, carpet testing, motors, lighting, common criteria, etc.)

D. Funding

NVLAP is a fee supported program and operates from the money it receives from its enrolled laboratories. The cost of accreditation varies from program to program. It also varies from year to year because an on-site assessment is required every two years. For the environmental program/field (which includes bulk asbestos fiber analysis and airborne asbestos fiber analysis), the fees associated with accreditation include:

- an initial application fee of $500;
- an administrative/technical support fee (assessed annually on a laboratory's anniversary of initial accreditation) of $4,000;
- an on-site assessment fee (conducted before initial accreditation, during the first renewal year, and every two years thereafter); this cost depends on the type of analysis being conducted ranging from $2,400 for bulk asbestos fiber analysis to $2,950 for airborne asbestos fiber analysis to $3,300 for both analyses combined;
- and a proficiency testing fee (assessed annually on a laboratory's anniversary of its initial accreditation) which is variable and sometimes conducted by outside testing services.

E. Assessment/Accreditation

Laboratory assessments are conducted by technical experts that NVLAP has trained to be auditors. NVLAP has a documented procedure to ensure the proper selection, training and

monitoring of its assessors. These technical experts can be NIST or NVLAP employees, however, the vast majority are contracted by NVLAP to be assessors.

Over the years, there have been numerous laboratories that have lost their accreditation (probably hundreds). Most of these occur because the lab is suspended due to severe deficiencies identified during an onsite assessment or for poor performance in proficiency testing. However, they can also be suspended for administrative reasons, such has failure to pay the required fees. Most of these labs regain their accredited status when they have proven to NVLAP that all deficiencies have been effectively resolved.

The American Association for Laboratory Accreditation
(A2LA)
5301 Buckeystown Pike Suite 350
Frederick, MD 21704
Phone: 301-644-3248
Fax: 301-662-2974
http://www.a2la2.net

A. Initiation of the Program

The ACIL (American Council of Independent Laboratories), which is a trade association representing independent commercial scientific and engineering firms, observed the need for the creation of a private accreditation program. Thus, in 1978, the American Association for Laboratory Accreditation (A2LA) was established as a non-profit, public service, membership society and has been accrediting laboratories ever since 1980.

A2LA began to seriously grow in 1989/1990 when General Motors began to recognize and require A2LA accreditation for the testing which supports their products through their GP-10 document (Evaluation and Accreditation of Supplier Test Facilities). Over the years, A2LA's reputation has grown and the organization has been recognized by a number of public and private sector organizations.

Accreditation through A2LA is voluntary and therefore it is usually driven by specific entities (e.g., regulators, industry bodies, etc.) who want confidence in the test data that they receive from laboratories. A2LA is an independent organization which means it is not governmentally mandated, however, A2LA is recognized by certain government agencies (e.g., EPA, NIST).

B. Characteristics of the Program

A2LA covers many fields of accreditation including: (1) acoustics and vibrations, (2) animal drug testing, (3) automotive EMC (Electromagnetic Compatibility) program, (4) biological, (5) site testing and calibration program requirements, (6) chemical: coal, (7) chemical: plastics, (8) chemical: rubber, (9) chemical: paper, paperboard, and pulp, (10) chemical: paint, (11) construction materials testing program, (12) environmental program, (13) environmental lead program, (14) food chemistry program, (15) food microbiology program, (16) geo-technical engineering program, (17) mechanical, (18) Kentucky Underground Storage Tank program , (19) non-destructive testing program, (20) putting green materials testing program, (21) thermal, and (22) Wyoming LAUST (Leaking Aboveground and Underground Storage Tank) program . In total, more than 1,600 laboratories have been accredited in the above fields.

A2LA has received recognition throughout the U.S. and the world. The following are examples of the types of recognition A2LA has received: (1) Mutual Recognition Arrangement with the Asia Pacific Laboratory Accreditation Cooperation (APLAC); (2) Bilateral Mutual Recognition

Agreement with the European Cooperation for Accreditation (EA); (3) Mutual Recognition Arrangement (MRA) with the International Laboratory Accreditation Cooperation (ILAC); (4) Mutual Recognition Arrangement with the National Cooperation for Laboratory Accreditation (NACLA); (5) the Federal Government; (6) state governments (e.g., GA, KT, NM, TX, WA, and WY); and (7) private sector (e.g., automotive industry, Nuclear Management Company, Safety Equipment Institute (SEI), United States Golf Association)

C. Program Operations

The international standard ISO/IEC 17025:1999 is the basis for the accreditation provided by A2LA. This standard not only requires a quality system and manual in the laboratory but also requires that the laboratory be found competent to perform specific tests/calibrations.

The process for accreditation through the American Association for Laboratory Accreditation includes several steps. First, the applicant laboratory completes and returns an application for accreditation with payment. A2LA reviews the application documents and an appropriate assessor(s) is assigned, with laboratory concurrence. The assessor contacts the laboratory to discuss the scheduling of an on-site assessment and requests the quality documentation. Once documentation is reviewed for completeness, the assessment is scheduled with the assessor(s). The assessment or the pre-assessment is then performed and includes: entry briefing, records, sample handling, interviews with technicians, demonstrations of tests/calibrations, examination of equipment and calibration records, review of quality documentation, written report of assessor's findings, and exit briefing. The laboratory responds to any deficiencies with a written corrective action response and the corrective action is reviewed by the A2LA staff and, once complete, is forwarded to the Accreditation Council, which makes decisions on accreditation, for a vote. Accreditation is granted when affirmative votes are received, all concerns are resolved, and all fees are paid in full.

A2LA maintains a full-time staff to provide the executive and administrative services of the Association. A2LA is governed by a Board of Directors. The Board membership represents interests of industry, labor, laboratories, government, and other professions. The Board maintains an Accreditation Council and a Criteria Council. The Accreditation Council (AC) makes decisions on granting, denying, or withdrawing accreditation, based on the assessment documentation provided by A2LA's assessors and the laboratory's response to any deficiencies cited. The Criteria Council approves specific criteria deemed necessary for particular fields of testing or testing technologies.

Until June of 2000, the general criteria for accreditation were based on ISO/IEC Guide 25-199 requirements. However, A2LA is now transitioning to ISO/IEC 17025, ISO/IEC Guide 25's replacement. The Transition is expected to be complete by December of 2002.

A2LA may also use existing consensus standards (e.g., ASTM E543) as appropriate or other consensus groups to formulate any specific criteria needed. All substantial new program requirements undergo, as appropriate, peer review by advisory committees and approval by the Criteria Council.

D. Funding

A2LA is funded by dues from members, fees charged to applicants, donations, revenue from the administration of training courses, and contracts and grants. Most of A2LA's resources are used to monitor the performance of applicants. Fee schedules are adopted and approved by the Board of Directors and are provided as part of the application package for each program.

Although accreditation is granted for two years, an annual fee is required to continue accreditation into the second year. There is a discount of $400 for more than one laboratory location and/or more than one field of testing. The annual fee for the first field/lab is $1,300 and the annual fee for two or more field(s) and/or lab(s) is $900 each.

Other fees incurred by laboratories seeking accreditation include:

- the initial application fee, which is a one time fee of $1,000 for the first facility and $800 for each additional facility.
- assessment costs which include an assessor deposit of $4,000 for one laboratory in one field plus $2,000 for each additional laboratory and/or field**.** After the assessment takes place, the laboratory is billed (or refunded) the difference between the actual costs and the assessor deposit. Actual costs can vary significantly depending upon a laboratory's size, desired scope of accreditation, and adequacy of its preparation for the assessment. Actual costs are computed based on: (1) total assessment time at $800 per 8-hour day per assessor; (2) travel (airfare, rental car, or private auto @ IRS allowable rate); and (3) accommodations and miscellaneous (hotel, meals, parking, calls, etc.).
- assessment time which can take from 1 to 5 days in the laboratory with additional time taken for preparation and report writing. If travel takes more than two hours, an additional cost at one half the assessment rate is added for each additional hour.

E. Assessment/Accreditation

A2LA's assessment of laboratories is conducted by contracted technical assessors who have been trained and approved by A2LA. The program recruits the assessors, trains them and then monitors their performance. The training sessions and meetings are conducted during the Annual A2LA Assessor Conclave. In addition, on-going monitoring of assessor performance and communications is conducted via a controlled e-mail distribution system, which helps to ensure uniform interpretation of the criteria and improve assessor performance.

There are several ways in which assessor performance is evaluated on a continual basis and these include:

· The performance of all new assessors is evaluated during their first on-site assessments. *SOP 023, On-Site Evaluation of Assessors* describes the procedures to be followed by the evaluator when reviewing the performance of an assessor.

- The Accreditation Council (AC) formally evaluates every assessor report they receive during the assessment voting period. These evaluations are used to improve performance and identify any weaknesses that need to be corrected. Feedback from clients is also considered in evaluating and guiding each assessor. Staff provides assessors with a summary of their AC evaluation annually. (Note: Accreditation Council members do not contact assessors directly. All contact is made through the A2LA Staff).

- At the conclusion of each accreditation/re-accreditation/surveillance process, clients are surveyed about their assessor performance. Survey feedback is provided to the assessors when warranted.

- Approved assessors on-site assessment performance is evaluated after their first year and then at least every three years thereafter or as deemed necessary.

Complaints from laboratories or other entities are handled through formal complaint handling procedures with an appeals process. A final appeal is made to the A2LA Board of Directors. Laboratories are also invited to offer suggestions for improvement through the website action request site.

Over the past years, laboratories have lost their accreditation (or not achieved it at all) if they have not meet the requirements set forth by A2LA. In addition, those laboratories that violate the conditions for accreditation can have their accreditation suspended (or withdrawn if no corrective action is taken on the suspension). Laboratories can re-apply for accreditation, if it is lost, once they have resolved their issues to A2LA's satisfaction.

National Association of Testing Authorities, Australia (NATA)
7 Leeds Street
Rhodes NSW 2138
Phone: 61 2 9736 8222
Fax: 61 2 9743 5311
http://www.nata.asn.au

A. Initiation of the Program

NATA is Australia's government-endorsed provider of accreditation for laboratories and similar testing facilities. It is an independent, private, not-for-profit company, operating as an Association and owned by its members. NATA was established in 1947. The fields of testing originally in the program included Metrology, Mechanical, Electrical, Optics and Radiometry, Heat and Temperature Measurement, Non-destructive testing, and Chemical and Biological Testing. In 1963, the Acoustics and Vibration Measurement program was added and in the early 1980s, the Medical (Pathology) program was included as a result of a decision between the College of Pathologists and NATA. In more recent years, programs have been established in Personnel Accreditation, Inspection, Reference Materials Providers, Proficiency Testing Service Providers, Veterinary, Forensic Science, Good Laboratory Practice and information technology.

The drivers for the continuance of the program are many and include government requirements (particularly for the pathology program), prestige for the accredited laboratories, an independent auditing system, market forces, and the facilitation of international trade. The main changes in the organization since its inception include the addition of new programs, the addition of a proficiency testing component, a shift to a more international focus, compliance with international standards, and government recognition.

B. Characteristics of the Program

The fields of accreditation that are covered by the NATA program are listed above. Several environmental laboratories have been accredited through NATA for a wide range of tests including residues, pollutants, soils, noise and air/water issues. Overall, 2,560 laboratories have been accredited by NATA.

NATA has been formally recognized by several organizations. Internationally, NATA: (1) has established mutual recognition agreements with over 33 other laboratory and inspection accreditation bodies in 24 economies; (2) is an active participant in international cooperative organizations such as the International Laboratory Accreditation Cooperation (ILAC) and is a signatory to the ILAC Arrangement; (3) holds Designating Authority status for laboratory and inspection body recognition from the Commonwealth government; (4) has accredited more than 40 overseas laboratories; (5) liaises with other international bodies such as BIPM/OIML (Bureau Internationale des Poids et Mesures/International Organization of Legal Metrology), ISO/IEC, IAF

(International Accreditation Forum), and the WTO; and (6) provides input to a number of international committees such as ISO/REMCO (REMCO is ISO's committee on reference materials), IUPAC (International Union of Pure and Applied Chemistry) and the OECD (Organization for Economic Cooperation and Development)Working Group on Good Laboratory Practice.

C. Program Operations

NATA is governed by an appointed/elected Council (45 members) and a Board of Directors (7 members of the Council), defined in the association's By-laws and Articles of Association. There is a Chief Executive, Deputy Chief Executive, a management committee and other divisional managers and scientific staff.

NATA has a secretariat of approximately 110 people employed by NATA, spread across most Australian capital cities, who provide day to day operations. The secretariat includes many scientific staff who administer and undertake the audits of applicants and accredited testing organizations, operate the various NATA proficiency testing programs, and provide training services. These staff are complemented by thousands of technical experts who volunteer their time to assist on NATA's various technical committees and to evaluate the technical competence of laboratories.

NATA is guided and monitored by its Board of Directors, drawn from its Council which is comprised of elected Association members and representative from industry, government and professional bodies. Technically, NATA's competence as an accreditation provider is regularly evaluated by it mutual recognition partners from Europe, North America, and the Asia-Pacific region, which ensures that its operation remains consistent with international practices.

NATA accredits laboratories against criteria based on the internationally recognized standard ISO/IEC 17025: 1999. Inspection facilities are accredited against ISO/IEC 17025: 1998. Other standards are also used including ISO 17020 for Inspection accreditation, OECD Codes of Good Laboratory Practice (GLP) published by OECD's Environment Directorate to cover NATA's GLP accreditation program, and the National Pathology Accreditation Advisory Council's guidelines, published by the Australian Government's Department of Health and Aging, for the accreditation of medical laboratories.

Generally laboratories participate in the program on a voluntary basis but there are some areas where it is mandatory (e.g., the Medical testing program is a directive of the Australian government).

D. Funding

The NATA organization is primarily funded through fees received from its accredited laboratories and those seeking accreditations. Applications are accompanied by a fee and each

accredited laboratory pays annual fees. Other fees are collected from training services, participation in proficiency testing programs, sale of publications, etc.

In addition to the application fee of $1500, there is an advisory visit ($155/hour), documentation review ($155/hour), and initial assessment fee ($155/hour). Annual membership fees include an initial fee based on technical units (1 technical unit: $2335, 2 technical units: $3625, 3 or more technical units: $4915). A technical unit is a measure of the assessment effort required to service an accredited laboratory per day. If a laboratory is engaged in a wide scope of accreditation, then the number of assessors required to fully evaluate that laboratory's operations would be approximately equal to the range of disciplines within that laboratory's scope of accreditation. Membership fees are also dependent on the distance of the accredited organization from a capital city General Post Office (GPO) in a state where there is a NATA office. Laboratories over 100 km from the GPO pay more to cover the cost of servicing them.

Additional fees incurred by the laboratories include: (1) follow up initial assessment visits and follow-up reassessment visits charged at $155/hour for all time spent servicing these activities (including preparation, on-site visits, report writing and post assessment activities); (2) certificates of accreditation; and (3) additional/amended certificates: $63.

E. Assessment/Accreditation

NATA makes use of technical experts for its laboratory assessments. NATA has access to nearly 3000 technical experts who volunteer their time to accompany NATA's scientific staff to evaluate the technical competence of laboratories and to provide additional technical input to NATA's other activities. All assessors are trained by attending a specific training course and are also on-site trained by experienced assessors.

In the case of disputes, procedures are provided in the organization's By-laws (available on the website) and in their internal manuals (not available to the public). The general procedure involves the recording of the dispute, acknowledgment that the dispute is being addressed and the completion of a full investigation to resolve the dispute or complaint in as short a time as possible.

About 4-5 laboratories lose their accreditation each year because the criteria as detailed in ISO 17025 (and other standards) are not met. Some of these laboratories are re-evaluated (and reaccredited/not accredited) while others choose not to seek re-admission.

International Accreditation New Zealand
(IANZ)
Private Bay 28908
Remuera, Auckland 1136
New Zealand
Phone: +64-9-5256655
Fax: +64-9-5252266
E-mail: info@ianz.govt.nz
http://www.ianz.govt.nz

A. Initiation of the Program

International Accreditation New Zealand (IANZ), established in 1972, is the national authority for the accreditation of technical and professional services. It is part of the New Zealand and international Conformity Assessment structure which is formed by three entities:

- Government - establishes national accreditation authorities which establish Mutual Recognition Arrangements with their overseas counterparts, enabling test and inspection reports and certificates of compliance from New Zealand to be accepted in export markets.

- Accreditation Bodies - including International Accreditation New Zealand (IANZ) and Joint Accreditation System for Australia and New Zealand (an international body established by Treaty in 1991 and jointly owned by the two governments - accredits systems certifiers, product certifiers and personnel certifiers against international standards)

- Testing, Inspection or Certifying Bodies

A diagram of the New Zealand accreditation structure is provided on their web site.

IANZ is one of two operating arms of the Testing Laboratory Registration Council which was established by an Act of Parliament in 1972. The Testing Laboratory Registration Council is a statutory body of the New Zealand Government and is part of New Zealand's technical conformity assessment infrastructure. The Council's accreditation and training programs operate as International Accreditation New Zealand (IANZ). The Council's management systems certification and business assessment programs are undertaken by a wholly-owned subsidiary company, Telarc Limited (www.telarc.co.nz).

In the late 1960s, the New Zealand authorities became concerned at the lack of any check on the competence of testing and calibration laboratories in New Zealand. The Australian laboratory community had established a National Association of Testing Authorities (NATA) to accredit laboratories on the basis of technical competence to undertake specific tests or measurements. The NATA program, begun in 1947, was broad spectrum, covering all fields of testing and was, at that time, the only one of its kind in the world.

Following a visit by New Zealand officials to the NATA program, the New Zealand government decided to establish a government agency to provide similar assurance of the quality of testing in New Zealand. The Testing Laboratory Registration Act was passed by Parliament in 1972 and the Council was formally established on January 1, 1973.

The Council adopted Telarc New Zealand as its operational name. Telarc New Zealand became the second such body in the world and was closely modeled on NATA. Telarc's initial task was to establish a program for registering (accrediting) laboratories as competent to undertake specific tests or measurements. The first Telarc Registered Laboratory accreditations were granted to New Zealand Aluminium Smelters and SGS Qualitest Division in 1975.

Over the next decade, New Zealand's economic focus changed. After many years as a traditional producer of agricultural commodities, largely for the British market, New Zealand found itself having to broaden its economic base into processing and manufacturing and to explore new markets in places such as the United States and Japan. The government recognized that, if New Zealand were to compete on the world market, action was needed to improve the quality of their goods and services.

Around this time, the British developed a standard for the management of business processes to ensure that products and services were consistent and fit for purpose. Businesses could be independently audited against this quality management system standard to ensure that their systems were maintained and improved. Similar standards were also developed in Canada and Australia.

In 1983, the Testing Laboratory Registration Act was amended to give the Council responsibility for introducing quality management systems into New Zealand and establishing a program to register companies that complied with the quality management systems standards. The Telarc Registered Supplier program commenced in 1984, initially using the British, Canadian and Australian standards until 1987, when the international quality management systems standards, the ISO 9000 series, were published. New Zealand's first ISO 9000 certificate was presented to UEB Packaging Limited in 1987.

In 1988, the Testing Laboratory Registration Act was amended again, to incorporate the activities of the former New Zealand Design Council. In 1991, the Testing Laboratory Registration Council was also given responsibility for managing New Zealand's official environmental labeling program, Environmental Choice New Zealand, on behalf of the Minister for the Environment.

In the 1990s, and particularly since the conclusion of the GATT (General Agreement on Tariffs and Trade) Uruguay Round, international conformity assessment systems have evolved as a hierarchy. Accreditation bodies are usually owned or endorsed by government and operate on a non-profit basis. The Council's accreditation of laboratories and inspection bodies was in this category. It is also at this level that the Council negotiates Mutual Recognition Arrangements for testing and inspection with counterpart bodies overseas in support of New Zealand exports.

Certification is another level of conformity assessment, and organizations that certify management systems operate in the commercial sector. By 1990, several other organizations were offering management system certification in New Zealand. The New Zealand and Australian

governments established the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) to accredit these certification bodies.

The Council's historical position, as both the national authority for the accreditation of testing and inspection facilities and a certification body for management systems, became anomalous in terms of international trends. A number of regulators in New Zealand also wanted to see the two activities separated to avoid any possible conflict of interest in the accreditation of technical competence activities for regulatory purposes.

On July 1, 1997, the Council's accreditation division was renamed International Accreditation New Zealand (IANZ). All accreditation activities previously undertaken in the name of Telarc New Zealand are now assumed by IANZ. This includes all Mutual Recognition Arrangements with counterpart accreditation bodies in New Zealand's trading partners. The Council's training division, the New Zealand Quality College now operates as a division of IANZ. IANZ also manages the Environmental Choice New Zealand program on behalf of the Minister for the Environment.

The Council's certification activities are now undertaken by Telarc Limited. This includes quality management systems certification (the ISO 9000 series and QS 9000), the certified environmental management system (ISO 14001), certification to the Telarc Q-Base Code for small and medium enterprises and other business assessment programs.

IANZ operates under the Public Finance Act and ISO /IEC Guide 58:1993. The major continuance for IANZ is market driven. However, many New Zealand regulators require/accept accredited test reports as a means of meeting their regulatory requirements. Laboratories and inspection bodies also frequently seek accreditation when there is no regulatory mandate primarily because they see the advantages to them directly from being accredited by IANZ.

B. Characteristics of the Program

The fields of accreditation covered by IANZ include biological, chemical, dairy, electrical, gas cylinder, meat, mechanical, medical, metrology and calibration, physical, and wool. The scopes of accreditation within these fields include environmental laboratories. Overall, more than six hundred organizations in New Zealand are accredited by IANZ.

IANZ represents New Zealand in the International Laboratory Accreditation Cooperation (ILAC), which groups over 40 nationally recognised accreditation authorities worldwide, and in the regional grouping, Asia Pacific Laboratory Accreditation Cooperation (APLAC). APLAC is recognised by regional governments as a Specialist Regional Body within Asia Pacific Economic Cooperation (APEC). IANZ is a signatory to the ILAC and APLAC mutual recognition arrangements.

C. Program Operations

Accreditation services are split into specific programs, each with its own program manager. IANZ accreditation services and management staff oversee day to day operations. The CEO and the Testing Laboratory Registration Council provide oversight to the organization. Criteria for accreditation is developed by IANZ, in conjunction with professional advisory committees. Each program has it own specific professional advisory committee consisting of technical experts from outside IANZ.

Accreditation by IANZ is both voluntary and required. Many New Zealand regulators (e.g., Occupational Safety and Health Service, Food Safety Authority, Ministry of Health, etc) require laboratories to be IANZ accredited (or Mutual Recognition Arrangement partners) for their results to be accepted as meeting regulatory requirements.

D. Funding

The IANZ program is entirely supported from fees collected from its clients. No government or taxpayer funding is used for any of its activities. The cost of accreditation for laboratories varies depending on the size of the laboratory and fees are charged on a time plus expenses basis. For a small (one or two person) lab, the annual fee could be as small as NZ$5,000 (equal to about half that amount in US dollars). For a large medical testing laboratory, with a large scope, the fee could be around NZ$50,000. These fees are only examples, and should not be considered maxima and minima. The "typical" fee would be less than NZ$10,000 for most labs.

E. Assessment/Accreditation

The on-site assessments of laboratories are conducted by IANZ staff plus technical experts. The IANZ staff are always the lead assessor for any site assessment. IANZ has a rigorous review and quality improvement program to ensure assessments are consistent and appropriate.

In the case of disputes, IANZ has a formal disputes and appeals mechanism in place. Over the last five years, several labs have lost their accreditation for not meeting the requirements for accreditation. All have been reaccredited, or are going through the process to obtain reaccreditation.

College of American Pathologists (CAP) Laboratory Accreditation Programs
325 Waukegan Road
Northfield, IL 60093-2750
Phone: 800-323-4040
Fax: 847-832-8000
http://www.cap.org

A. Initiation of the Program

The CAP Laboratory Accreditation Program (LAP) was established in 1961. It was created with the primary objective of improving the quality of clinical laboratory services throughout the United States, through voluntary participation, professional peer review, education, and compliance with established performance standards. In 1967, a Federal Act, the Clinical Laboratory Improvement Act, was passed which greatly paralleled the requirements of the CAP program. The Center for Medicaid and Medicare Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through CLIA. The objective of CLIA is to ensure quality laboratory testing. In 1988, the Federal government amended the CLIA, establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The amendment broadened the scope of CLIA to cover all medical laboratories and made provisions for recognition of laboratories.

CMS also approves accrediting organizations and determines if the organizations' requirements are equivalent to or more stringent than CMS's regulatory requirements. An approved accrediting organization can inspect a lab in lieu of CMS. In 1994, the CAP program applied for recognition through CLIA and gained approval in 1996. In 2001, CAP was granted approval for another 6 years as an accreditation body. This approval means that laboratories may elect to use inspection and accreditation by CAP in lieu of inspection and licensure by an agent of the government (usually a state).

The CAP program expanded in 1988 with the Forensic Urine Drug Testing (FUDT) accreditation program and in 1993 added the Reproductive Laboratory Program (RLAP), directed jointly with the American Society of Reproductive Medicine (ASRM).

Recent improvements to the CAP Laboratory Accreditation Program include: (1) audio conferences; (2) on-line access to current checklist questions; (3) accessibility to CAP through an e-mail address strictly devoted to accreditation issues; (4) a re-application process with pre-populated forms that require only the laboratory's changes; (5) an opportunity to provide a custom profile of the laboratory's organizational structure that aids in the inspector assignment; and (6) improved organization of the CAP inspection materials.

The main driver for the continuance of the CAP LAP program is the recognition that the program has among medical laboratories and the prestige that accompanies accreditation through the program.

B. Characteristics of the program

In addition to the general Laboratory Accreditation Program, the CAP brings also provides accreditation in the following areas:

- Reproductive Laboratory Accreditation (RLAP): In collaboration with the American Society for Reproductive Medicine (ASRM), the CAP has developed an accreditation program specifically designed for the unique needs of reproductive laboratories.

- Forensic Urine Drug Testing (FUDT) Accreditation: This program has been designed with cooperation with the American Association for Clinical Chemistry (AACC) and is available for labs performing urine drug testing for nonmedical purposes (i.e., workplace drug testing).

In all, the CAP LAP program accredits over 6,400 laboratories worldwide. CLIA, which regulates all clinical laboratories, covers approximately 175,000 laboratory entities.

Over the years, the accreditation programs of the College of Pathologists have been acknowledged as programs of excellence. Certain regulatory agencies and other accrediting programs have officially recognized the value of the CAP Laboratory Accreditation Program:

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Centers for Medicare and Medicaid Services (CMS) -- The LAP has been approved as a private accrediting organization under CLIA by the CMS.
- State Licensure -- States also license clinical laboratories. The extent to which the CAP accreditation program is recognized by state governments varies.

C. Program operations

Management and operation of the three accreditation programs are the responsibility of the Commission on Laboratory Accreditation (CLA). The CLA is a group of qualified pathologists appointed by the president of CAP. The Commission is composed of a Chair, a Vice Chair and Regional and Special Commissioners (all certified pathologists). The CLA meets three times each year to develop standards, guidelines, and policies for the LAP. In addition, an Executive Committee of the CLA meets frequently to consider urgent policy/procedure issues as well as individual laboratories with unusual inspection or public findings.

Each Regional Commissioner is responsible for all accreditation activities within a specific geographic region. This includes the timely assignment of inspectors, review of inspection findings, and resolution of issues that may arise over accreditation decisions. The Regional Commissioners are assisted by Deputy and State Commissioners. Other commissioners oversee the revision of the inspection Checklists; develop inspector training materials; address state and federal legislative and regulatory issues; and edit the Laboratory Accreditation Newsletter. In addition, the Commission uses the expertise of numerous CAP scientific resource committees to keep the program and its requirements current.

State and Division Commissioners are responsible for identifying and assigning inspectors for their geographic regions. They make sure that inspections are conducted on a timely basis and in accordance with Commission policy.

The application process starts with the laboratory seeking accreditation submitting an application to CAP. If the laboratory meets the initial criteria and is found to be eligible for accreditation, the State and Division Commissioners then identify an inspection team leader, which assembles an inspection team. The team leader is generally the director of a laboratory that has already been accredited through CAP and the team is the laboratory workers of that lab. The State and Division Commissioners are pathologists who are familiar with different laboratories and can match up appropriate labs for the inspection. Once a suitable inspection team is identified, the team leader contacts the laboratory and sets up an inspection date.

Once the inspection has taken place, the inspection findings are returned to the staff and a list of deficiencies found is also left with the laboratory. Inspection findings fall into two categories: Phase 1 and Phase 2. Phase 1 criteria are more general to the overall function of the laboratory and the tests that the laboratory performs. Phase 2 criteria relate more to the safety and health of the workers in the lab. Once the inspection has been completed, the laboratory has 30 days to correct and respond to the findings of the inspection team. For phase 2 deficiencies, the laboratory needs to provide a plan of corrective action as well as evidence of implementation. For phase 1 deficiencies, the laboratory only needs to provide a plan of implementation.

The response from the laboratory to the inspection findings is sent to the staff of CAP, which then reviews the response for adequacy. If the staff believes the laboratory to be compliant, then the findings of the inspection, the list of deficiencies, and the lab's response is sent to the Regional Commissioner who then reviews this packet of information and makes the final decision on accreditation.

Oversight for the CAP program is provided by both the CLA and by the Center for Medicare and Medicaid Services (CMS). CLA provides most of the direct oversight for the CAP program through the development of policies and standards. CMS provides more general oversight, which it does for all laboratories under the CLIA.

The standards developed by the CLA are the basis for the accreditation decision. Each of the three accreditation programs has its own standards. The standards, which have evolved through years of study and continuous review by the CLA, are approved by the CAP Board of Governors. The four standards that are used in the accreditation process deal with the director of the laboratory, the physical facility and safety of that facility, quality control and performance improvement, and inspection requirements (both by an external team and self-inspection). Detailed descriptions of all these standards is provided on the CAP web site.

D. Funding

Funding from the program mainly comes from the fees obtained from laboratories seeking accreditation. The fee is based on three components: the discipline/subdiscipline component, which

consists of a weighted point value assignment for each discipline and subdiscipline; the total annual test volume component; and the base fee, which covers the pre- and post-inspection technical and administrative services.

The point value is based on the average effort required to inspect that discipline or subdiscipline relative to others. As an example, on average it takes twice as long to inspect a Hematology section than a Parasitology section. Some disciplines, such as Cytogenetics, require specialty inspectors who cannot necessarily assist in inspecting other disciplines. This type of a situation is accounted for in the point value assigned to that discipline.

Generally, the fee is calculated by adding the points assigned to each discipline and subdiscipline that the laboratory performs, accounting for multiple occurrences of each discipline. To that subtotal, a test volume component is added and a fee/point applied. Finally, a base fee derived from the total points assigned to the laboratory is added.

The minimum fee would be approximately $900 and variations on the fee depend a great deal on the components listed above. There is an application fee for each laboratory which is included in the first years accreditation fee.

E. Accreditation/Assessment

The actual on-site assessments are conducted by personnel of laboratories already accredited by the CAP program. These inspection teams are selected by the State and Division Commissioners. The director of the lab serves as the inspection leader and his/her lab staff serve as the inspection team. The inspection team leader is trained by attending an inspector training seminar and participates in several inspections as a team member and generally has expertise in the area of the laboratory that they are to inspect.

If a laboratory wishes to challenge a particular finding, it states its disagreement in its deficiency response. The response needs to include documentation that demonstrates that the laboratory was in compliance at the time of the inspection. The Regional Commissioner reviews disputed items and determines if the deficiency can be removed from the record. To help resolve questionable citations, the Laboratory Accreditation technical staff may assist an inspector by telephone during the inspection. Several laboratories over the years have lost their accreditation for failure to meet the standards and criteria needed to gain and keep accreditation through the CAP program.

South African National Accreditation System (SANAS)
Building 10F, CSIR Campus
Meiring Naude Avenue
Brummeria
Pretoria, South Africa
Phone: +27 12 349 1441
Fax: +27 12 340 1449
http://www.sanas.co.za

A. Initiation of the Program

Accreditation in South Africa began in the 1980s with the establishment of the National Calibration Service (NCS). Initially, the NCS, which operated under the auspices of the CSIR (Council for Scientific and Industrial Research) accredited laboratories only in the field of calibration. Later, the National Laboratory Accreditation Service (NLA) was established and in 1994, the NLA became an independent company in line with international requirements pertaining to autonomy. Starting in 1995, the NLA began accrediting testing laboratories, assuming responsibility for laboratories previously accredited under a South African Bureau Standards System (SABS) referred to as SABS 0259.

In 1993, the government of South Africa, through the Department of Trade and Industry (DTI), recognized the need to create a single national accreditation system. Establishment of SANAS was approved by Cabinet in 1994. In 1995, the newly independent NLA was contracted to manage the establishment of SANAS. During July of that year, a working group was formed to finalize the organizational structure and constitution of SANAS and the new entity was created in January 1996.

SANAS was officially launched in August 1996 and after much effort from the new SANAS board, a Memorandum of Agreement (MOA) was signed with the DTI in December 1997. Through this MOA, SANAS was recognized as the single national authority for the accreditation of testing and calibration laboratories, inspection bodies, bodies for certification of quality and environmental management systems, and product conformity certification bodies. SANAS is also recognized as the national monitoring authority for GLP and GCP compliant facilities. The DTI reserves the right to extend this recognition to encompass other areas of accreditation as and if these arise.

B. Characteristics of the Program

SANAS accredits five different types of laboratories: certification bodies, calibration laboratories, testing laboratories, medical laboratories, and inspection bodies. The fields of accreditation within each laboratory include the following:

Certification Bodies	agriculture/forestry/fishing, chemicals and allied industries, clothing and footwear, coal and petroleum products, electrical engineering, food/drink/tobacco, instrument engineering, mechanical engineering, metal goods not elsewhere specified, metal manufacture, mining and quarrying, shipbuilding and marine engineering, textiles, vehicles, bricks/pottery/glass/cement, construction, distributive trades, gas/electricity/water, insurance/banking/finance/business services, leather/leather goods/fur, paper/printing/publishing, professional and scientific services, public administration/defense, timber/furniture, and transport and communication
Calibration Laboratories	air pollution, DC low frequency, dimensional, fiber optics, flow, force/hardness/torque, humidity, mass/volume, non-destructive testing, photometry, pressure, radiation dosimetry, radio frequency, temperature, time/frequency, vibration/rotational speed
Testing Laboratories	acoustics, air pollution, air speed, biological, chemical, construction/civil engineering, electrical, environmental, forensic, GLP compliant laboratories, mechanical, microbiological, performance, physical, and safety
Medical Laboratories	cytology, haematology, histopathology, immunology, microbiology, molecular biology, virology, veterinary
Inspection Bodies	food, gas test stations, risk assessment, textiles/leather/clothing/footwear, vessels under pressure

SANAS is recognized by the South African Government as the single national accreditation body that gives formal recognition that laboratories, certification bodies, inspection bodies, proficiency testing scheme providers and Good Laboratory Practice test facilities are competent to carry out their specific tasks. Overall, SANAS has accredited 242 calibration and testing laboratories, 154 medical laboratories, and 140 verification (legal metrology) laboratories.

C. Program Operations

SANAS has a Board of Directors who are elected from among its members and stakeholders, including government representation. Once elected, the board may co-opt a number of additional members in areas of expertise that are lacking. Among other duties, the Board is responsible for appointing the CEO of SANAS. The CEO is responsible to the Board for the development, direction, management and running of SANAS. The Board delegates to the CEO all authorities and necessary responsibilities to manage the day-to-day functioning of SANAS.

The management of SANAS is the responsibility of a management team under the direction of the CEO. The management team is made up of the CEO, Executive and Program Managers. The

SANAS Board assists the management team in the development of strategies and policies, and, in association with the relevant Approvals Committee (AC), the suspension of accreditation. AC's are established for each field of operation of SANAS and make decisions concerning the granting and continuance of accreditation. These decisions are reported to the SANAS Board on a quarterly basis at the board meetings.

In addition to approving decisions on accreditation, AC's also give advice to the SANAS board on other matters related to the activities of the AC for that specific field. Committee members are allowed to have membership on more than one AC. The CEO of SANAS is responsible for ensuring that all committees have the necessary impartiality. The Program Managers (PMs) are responsible for nominating potential members of AC's to the CEO and ensuring that the ACs have sufficient expertise.

SANAS operates in accordance with the requirements, criteria, rules and regulations laid down in the following documents:

- the Memorandum of Association–details the basic legal requirements to be complied with by SANAS
- the Articles of Association-details the rules and regulations of SANAS
- the requirements of the international standards ISO-IEC 17011: General requirements for bodies providing assessments and accreditation of conformity assessment bodies
- the requirements as stipulated in the various Memorandums of Agreement with the international bodies and the national regulatory bodies

In order for accreditation to be granted, an applicant facility must satisfy SANAS assessors that it complies with all SANAS requirements. A Lead Assessor, appointed for each assessment, is responsible for all documentation associated with the assessment. The Lead Assessor ensures that all details and forms associated with the assessment are completed for consideration by an Approval Committee, who may require further investigation and/or assessment. Once the Approval Committee is satisfied with the assessment, and on positive recommendation of the Lead Assessor, accreditation is granted.

The SANAS office records the completion of the initial accreditation process on the applicant facility's file and issues an accreditation certificate with a schedule detailing the scope of accreditation. The decision is communicated to the Board at the next board meeting. The CEO, SANAS, or his appointed deputy authorizes by signature the accreditation certificate and scope of accreditation.

Accreditation remains valid as long as the organization continues to comply with SANAS requirements. An accreditation certificate for a laboratory is re-issued every four years and for a certification body is re-issued every three years (after successful completion of a re-assessment) or as required by changes which can impact the facility's status (e.g., change to scope of accreditation or changes in location, phone number, senior staff, etc.).

If an accredited facility fails to continue to comply with accreditation criteria at any time before the expiration of its certificate, SANAS can withdraw the accreditation. In order to maintain accreditation, facilities must comply with SANAS requirements at all times. SANAS verifies

compliance by: (1) a surveillance visit approximately six months after the initial assessment; (2) surveillance visits that take place no more than every 18 months which follow the original assessment format but on a sampling basis and involve a technical assessment of the facility together with an assessment of the Quality Management System; and (3) annual proficiency tests for laboratory accreditation, where applicable. Complete re-assessment replaces the surveillance visit every fourth year.

The criteria which laboratories must comply with to obtain accreditation are contained in ISO/IEC Guide 25 and ISO/IEC 17025 and SANAS regulatory documents. Laboratories are assessed against the requirements of these documents where relevant.

D. Funding

SANAS fees are meant to cover the costs directly associated with accreditation and include an initial accreditation fee, annual fees, and training. Fees are approved by the finance committee and formalized in a fees document and subject to change from year to year. The PM's are responsible for ensuring that all accredited facilities are charged according to the documented fee structure where such a fee is applicable.

The costs involved in accreditation are listed in the table below (amounts are given in approximate US Dollars converted from South African Rand listed on web site):

Application fees:	
Application fee	$320
Documentation review (if documentation review takes more than one day, the applicant is charged at a rate of ~$200 per additional day)	$200
Extra copy of SANAS document manual	$28
Pre-Assessments (visit by one assessor for one day, excludes travel and documentation review)	$200
Initial Assessment:	
Minimum fee (include two assessor units; a unit is one assessor for one day or part of a day)	$830
Additional assessor units per day	$200
Evaluation of laboratory personnel (max of 3 candidates per examiner per day)	$200

Annual Fees:	
Minimum fee (includes two assessor units; lead assessor and technical assessor for one day)	$880
Each additional assessor unit	$200

The following provides an example of a fee calculation for a laboratory seeking accreditation:

> A small laboratory with one discipline (e.g., microbiology) where the scope of tests applied for can be assessed in one day would cost ~$880. This would allow the lead assessor and one technical assessor to assess the laboratory over a single day. If the scope of the tests applied for was such that it would take the two assessors another day, the fee would be $880 plus ~$400 for the additional day spent at the laboratory by the two assessors.
>
> A laboratory having more than one discipline would require three assessor units as a minimum. A lead assessor together with two technical assessors would be appropriate for the two separate disciplines. The minimum fee would therefore by ~$880 plus ~$200 for the additional technical assessor for one day. This gives a total of ~$1080. If this same laboratory had a scope of accreditation that required each of the assessors to spend an additional day at the laboratory, the fee would not be ~$1080 plus ~$600 for a total of $1680.

SANAS does charge fees for additional services provided outside of the initial accreditation process. These include the following:

- fees for extension of accreditation:
  - these fees, if part of a planned annual assessment with prior agreement of the lead assessor, are included as part of the annual fee unless additional technical time is required to cover the expanded scope
  - an extension that requires special arrangement is charged at a rate of ~$400 for the first day and ~$200 for each additional assessor day, plus transport costs and appropriate laboratory audit sample costs

- additional visits: any additional visits arranged by the client's request are charged at ~$240 per assessor per day, plus any additional costs

- clearance of non-conformances: in those instances where SANAS requires that clearance of non-conformances be verified by an additional on-site visit, these are charged for a rate of ~$240 for the first assessor unit excluding travel costs and each additional assessor is charged at a rate of ~$200.

E. Accreditation/Assessment

SANAS ensures that all its assessors are thoroughly familiar with all SANAS documentation and the accreditation process. SANAS Lead Assessors are required to comply with the requirements laid down in the SANAS document: "Qualifying and Monitoring of Assessors and GLP Inspectors". SANAS Lead Assessors are appointed by the Board to operate in specified areas (e.g., certification assessments, laboratory assessments, etc).

SANAS employs or contracts assessors to perform specific functions (e.g., assess a certification body, inspection body, or laboratory as a Technical or Lead assessor). Technical assessors for laboratories are those assessors who have been identified for their knowledge in a specific technical field and who have successfully completed the SANAS technical assessor training course. SANAS Lead Assessors are authorized to direct assessments, report findings and to evaluate proposed corrective actions in consultation with the Technical Assessor(s).

Each assessor is approved by SANAS and completes the relevant training and evaluation requirements prior to performing unsupervised assessments. The performance of all assessors is monitored over a period of at least four years to ensure consistent interpretation and application of the relevant guides and/or standards used. The Lead Assessor is responsible for reporting any concerns with respect to the performance of the assessors on the team to the relevant Program Manager.

The appropriate Approval Committee monitors the ongoing performance of Lead Assessors. Their ability to complete the assessment documentation and to compile an assessment report is continually monitored. If the assessment documentation gives the Approval Committee cause for concern regarding the performance of a Lead Assessor, Technical Assessor or the assessment itself, this is brought to the attention of the CEO who then takes the appropriate corrective action.

Cases of laboratory non-compliance with SANAS requirements are brought to the relevant Approval Committee, which may recommend suspension or termination. Such cases usually result from unsatisfactory assessments or from information passed to SANAS. The final decision on accreditation rests with the Board. However, the SANAS CEO, in consultation with the Finance Committee, acting alone may cancel accreditation for non-payment of fees after the appropriate formal warnings have been issued.

Facilities that go into voluntary suspension are given a period of three months from the date of suspension to adequately address the circumstances that caused the suspension. Facilities in voluntary suspension for longer than three months are required to apply to SANAS for permission to continue in voluntary suspension for each further three months.

Facilities who do not apply to SANAS for extension of the suspension have their accredited compliant status revoked by the Approval Committee after the initial three months. These facilities then have to re-apply as a new applicant if they wish to become accredited again and are liable for all costs associated with a new application including application fee and document review.

National Lead Laboratory Accreditation Program (NLLAP)
U.S. EPA
OPPTS/OPPT/NPCD
Program Assessment and Outreach Branch
Ariel Rios Building
Mail Code: 7404T
1200 Pennsylvania Ave., N.W.
Washington, DC 20460
Phone: 202-566-0493
Fax: 202-566-0469

A. Initiation of the Program

EPA established the National Lead Laboratory Program in 1993. It was established under the Congressional mandate stated in section 405(b) of the Toxic Substances Control Act (TSCA), which was enacted as part of the Residential Lead-Based Paint Hazard Reduction Act of 1992 (Title X of the Housing and Community Development Act of 1992). TSCA section 405(b) requires the EPA Administrator to establish protocols, criteria, and minimum performance standards for laboratory analysis of lead in paint films, soil, and dust. The Administrator may do so either by establishing a federally-operated laboratory accreditation program, or by issuing a determination that effective voluntary accreditation programs are in place and operating on a nationwide basis.

In order to establish a national accreditation program for laboratories conducting analyses for lead in paint, dust and soil matrices associated with the evaluation and control of lead-based paint hazards, EPA's Office of Pollution Prevention and Toxics draws upon the capabilities of private and public laboratory accrediting organizations. EPA establishes a Memorandum of Understanding (MOU) with each accrediting organization in recognition of its capability to perform adequate laboratory assessments meeting the conditions and requirements set forth by EPA.

Since its inception, NLLAP has reflected a Performance-Based Measurement System approach. The program does not restrict the use or recommend the use of any method or technology for the analysis of samples. NLLAP essentially consists of two components. The first component is successful participation in the Environmental Lead Laboratory Proficiency Analytical Testing (ELPAT) program administered by the American Industrial Hygiene Association (AIHA) in conjunction with the EPA and the National Institute for Occupational Safety and Health (NIOSH). The second component of NLLAP is a systems audit which is conducted by a laboratory accreditation body recognized by EPA.

One major change that has occurred in the NLLAP program since its inception is that initially the program covered only fixed laboratories, but was expanded to cover field operation (mobile)

laboratories in a Federal Register Notice of November 14, 1996 (Vol 61, Number 221, pp58408-58409). These types of laboratories were made eligible for recognition by NLLAP because they were designed to operate in a manner similar to that of the traditional fixed site laboratories (i.e., a sample is collected, prepared for analysis, and analyzed to obtain a result).

B. Characteristics of the Program

NLLAP does not actually accredit laboratories itself, but rather recognizes other accrediting organizations. In particular, it currently recognizes two organizations, the American Industrial Hygiene Association (AIHA) and the American Association for Laboratory Accreditation (A2LA).

AIHA's recognized program is the Environmental Lead Laboratory Accreditation Program (ELLAP), which accredits laboratories performing analysis of lead in environmental samples including paint, soil, dust wipes and air. A MOU with EPA declares that all laboratories accredited by AIHA for the analysis of lead in paint chips, dust wipes, and/or soil is recognized by NLLAP as competent of performing acceptable lead analyses.

A2LA's program covers the analysis of lead in various matrices and includes air, building debris, dust, paint (unapplied), paint chips (residue), soil, and water (drinking). The A2LA program offers a broader scope of accreditation and includes organizations engaged in environmental assessment activities in addition to those related to lead-based paint use identification. While A2LA accredits laboratories for any testing which they have been found competent to perform, the NLLAP includes only the matrices of paint, soil and dust and does not cover the analysis of test areas using in situ techniques.

As of October 2002, 130 laboratories have been accredited through these two accrediting bodies and are recognized by NLLAP.

C. Program Operations

Oversight of the NLLAP program is provided by EPA's Office of Pollution Prevention and Toxics (OPPT). This program office is responsible for: (1) recognizing organizations as recognized accrediting organizations and providing a list of those laboratories to the public, (2) providing guidance on NLLAP requirements to the accrediting organizations, (3) conducting evaluations of the accrediting organizations at least once every three years, and (4) accompanying, as seen fit, the accrediting organization's assessors during on-site visits in order to observe the performance of the NLLAP recognized organization's assessor in the field.

Accreditation bodies seeking EPA's recognition as an NLLAP accreditation body are evaluated by EPA. A checklist has been prepared to aid in assessing the effectiveness of the accreditation body. The criteria include: 1) compliance with ISO/IEC Guide 58—Calibration and Testing Laboratory Accreditation Systems—General Requirements for Operation and Recognition; 2) compliance with specific requirements set forth in the NLLAP Model Memorandum of Understanding; and 3) compliance with specific requirements set forth in "Laboratory Quality System Requirements," an appendix of the MOU.

All laboratories recognized by NLLAP are required to undergo on-site audits conducted by the accrediting organizations participating in NLLAP. Some of the areas evaluated include laboratory personnel qualifications and training, analytical instrumentation, analytical methods, quality assurance procedures and record keeping procedures. The laboratories must also perform successfully on a continuing basis in the Environmental Lead Proficiency Testing Program (ELPAT).

The ELPAT Program is a cooperative effort of the American Industrial Hygiene Association (AIHA), and researchers at the Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), and the EPA OPPT. The acceptable range for the ELPAT test samples is based upon consensus values from reference laboratories. A laboratory's performance for each matrix (i.e., dust wipes, soil, and air) is rated as proficient if their ELPAT results are within three standard deviations of the determined acceptable range for 75 percent of the ELPAT test samples.

The general requirements for laboratory accreditation organizations participating in the NLLAP are stated in ISO Guide 58, "Calibration and Testing Laboratory Accreditation Systems-General Requirements for Operation and Recognition" of ISO/IEC. Accreditation organizations must state their specific program requirements addressing the general requirements stated in ISO Guide 58. In addition, accreditation organizations are also required to:

- submit to EPA/OPPT for review their organizational quality manual (QM) and related documents which describe the quality system currently in place.
- establish and implement a training program and continuing education program for assessors
- perform a systems audit on applicant laboratories inclusive of an on-site assessment
- require that all laboratories applying for accreditation perform successfully in the ELPAT program.
- reevaluate laboratories accredited for lead analysis at a minimum of once every three years.
- provide to NLLAP accreditation information including the date the accreditation is effective, the accreditation expiration date and the matrices which the laboratory is accredited for, upon approval of an accredited laboratory.
- maintain records for a period of ten years of the terms of accreditation of each accredited laboratory including all complaints received from customers of the accredited laboratory.
- participate in meetings with EPA at least once every two years in an effort to help provide a formal evaluation of NLLAP.

D. Funding

There is no direct cost for the NLLAP program and EPA employs one full-time employee to direct and oversee the program. Accrediting organizations (e.g., A2LA and AIHA) are not charged to be recognized by NLLAP. However, laboratories that wish to apply for accreditation through

those accrediting organizations recognized by NLLAP do have to pay the fees associated with those accreditation organizations.

The cost for accreditation for laboratories through A2LA is provided earlier in this report in the section on the A2LA program. For AIHA, the cost of accreditation is as follows:

- initial accreditation fee of $400;
- annual accreditation fee of $900, includes participation in one program with additional programs costing $900 each;
- site assessments at $825 per day/per program (plus assessor's travel expenses) and
- proficiency testing programs which include an annual fee and fees for the types of samples required (e.g., paint chip, soil, and/or dust wipe); these fees vary depending on the number of sets of samples requested. For example, for one set of samples, the annual fee is $245 and the costs for the paint chip, soil, and dust wipe samples are $130, $130, and $145, respectively. For 4 sets of samples, the annual fee is $900 and the costs for the paint chip, soil, and dust wipe samples are $450, $450, and $500, respectively.

E. Accreditation/Assessment

On-site assessments of the accredited laboratories are required by NLLAP to be conducted by personnel of each accredited organization, applying their general and environmental program requirements. NLLAP personnel can choose to accompany assessors as deemed necessary on these site assessments.

NLLAP conducts its own audits of each accrediting organization it recognizes every three years to make sure these organizations are continuing to comply with EPA's requirements.

Assessors are required to participate in a training program as part of NLLAP's requirements. These training programs can be established using EPA's developed curriculum guidance document or can be developed by the accrediting organization as long as it is reviewed by EPA.